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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------------|------------------|
| 10/068,167 | 02/05/2002 | Terrance D. Peabody | IOI-389 | 8049 |
| 24978 | 7590 | 11/04/2004 | | |
| GREER, BURNS & CRAIN 300 S WACKER DR 25TH FLOOR CHICAGO, IL 60606 | | | EXAMINER MARMOR II, CHARLES ALAN | |
| | | | ART UNIT 3736 | PAPER NUMBER |
| DATE MAILED: 11/04/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,167

Applicant(s)

PEABODY ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 28 and 30-35 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed June 18, 2004. The Examiner acknowledges the amendments to claims 1, 5, 6, 10, 18, 19, 25, 28 and 30; the cancellation of claim 27; and the addition of new claims 34 and 35. Claims 1-26 and 28-35 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 recites the limitation "the means for marking" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is a "means for guiding the marking of the desired bone member" recited in claim 30, but it is unclear whether this element is the same element as "the means for marking" recited in claim 32 or if these are separate and distinct elements of the system.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 7, 30, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerhardt ('162). Gerhardt teach a measurement member that is capable of assisting in locating a prosthetic device during an orthopedic procedure. The measurement member includes a marking guide **32**; a stop plate **18**; a ruler **10,12** coupled to the marking guide and to the stop plate; and a locking mechanism **16,24** that cooperates with the ruler to permit selective adjustment of the distance between the marking guide and the stop plate by moving the stop plate with respect to the ruler. The claim language does not define any particular structure characteristic of the respective marking guide and stop plate; therefore, since leg **32** is capable of guiding marking of a bone member and since leg **18** is capable of being used as a stop member, these elements meet the claim limitations. The marking guide and the stop plate are capable of being utilized in a manner noninvasive to the bone tissue. The base of locking mechanism **16** includes an opening and the ruler is configured to slide within the opening.

6. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Malek Afzali ('163). Malek Afzali teach a measurement guide that is capable of being used for noninvasive measurement of bone tissue during an orthopedic procedure. The measurement member includes a non-invasive marking guide **7**; a noninvasive stop plate **2**; and a ruler **8** coupled to the marking guide and to the stop plate. The noninvasive stop plate **2** is pivotable with respect to the ruler in order to facilitate transverse placement with respect to the ruler against an end surface of a bone. The claim language does not define any particular structure characteristic of the respective

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marking guide and stop plate; therefore, since member 7 is capable of guiding marking of a bone member and since member 2 is capable of being used as a stop member, these elements meet the claim limitations.

7. Claims 1-7, 10, 11, 16-18 and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrante et al. ('401). Ferrante et al. teach a measurement member that is capable of assisting in locating a prosthetic device during an orthopedic procedure. The measurement member includes a marking guide 46; a stop plate 96; a ruler 28,30 coupled to the marking guide and to the stop plate; and a locking mechanism at lock screw 26 that cooperates with the ruler to permit selective adjustment of the distance between the marking guide and the stop plate by moving the stop plate with respect to the ruler 30. The marking guide and the stop plate are themselves noninvasive, and therefore are capable of being utilized in a manner noninvasive to the bone tissue. The claim language does not define any particular structure characteristic of the respective marking guide and stop plate; therefore, since surface 46 is capable of guiding marking of a bone member and since plate 96 is capable of being used as a stop member, these elements meet the claim limitations. The stop plate is pivotably coupled to the locking mechanism to permit positioning of the stop plate at desired angles with respect to the ruler at lock screw 108 to facilitate transverse placement with respect to the ruler against an end surface of a bone. The stop plate is configured such that it is capable of abutting the distal femoral condyles or the proximal end of a tibia. The stop plate may be locked at desired angles with respect to the ruler at lock screw 108. The desired angles are inclusive of approximately 84°, 90° and 96°. The locking mechanism includes an opening and ruler portion 28 is configured to slide

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within the opening. Release mechanism **26** selectively releases the ruler for sliding movement through the opening.

8. Claims 1, 7, 10, 11, 16, 17, 19-26, 28 and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodge ('178). Claims 19-26, 28 and 29 of the present application include the transitional phrase "comprising" which is inclusive or open-ended and does not exclude additional, unrecited method steps; and furthermore, the claim language does not require the claimed method steps to be performed in any particular order. Hodge teaches a method for utilizing a measuring device to facilitate an orthopedic procedure. The device includes a marking guide **94**; a stop plate **50**; a ruler **100** coupled to the marking guide and to the stop plate; and a locking mechanism at lock screw **46** that cooperates with the ruler to permit selective adjustment of the distance between the marking guide and the stop plate by moving the stop plate with respect to the ruler. The marking guide and the stop plate are themselves noninvasive, and therefore are capable of being utilized in a manner noninvasive to the bone tissue. The method includes the steps of setting a selected distance between a noninvasive stop plate and a noninvasive marking guide movably coupled to the stop plate by changing the position of the stop plate relative to the marking guide along a ruler by changing the position of the marking guide along a ruler by moving the stop plate with respect to the ruler; abutting the noninvasive stop plate against an end of a member to be measured; placing the noninvasive marking guide along bone tissue of the member the selected distance from the stop plate for marking of the bone tissue; marking the bone tissue; and lifting the noninvasive stop plate and the noninvasive marking guide from the member. The bone tissue may be removed from the member in an

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oncological procedure or by performing a revision procedure. The noninvasive stop plate may be pivoted to a desired angle that allows it to abut a pair of distal femoral condyles of the member. The stop plate alternatively may abut the proximal end of a tibia.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerhardt ('162) in view of Kim ('891). Gerhardt teaches all of the limitations of the claims except that the ruler includes a flat side and a series of periodic grooves, and that the release mechanism includes at least one corresponding protrusion to engage selected grooves. Kim teaches a measurement device including a pair of arms 50, a ruler 114 comprising a flat side and a series of periodic grooves 88 coupled to the arms, a locking mechanism 90 and a handle 58 coupled to the locking mechanism. The locking mechanism includes an opening 64 through which the ruler is received and a release mechanism to selectively release the ruler for sliding movement through the opening. The release mechanism includes at least one protrusion 92 for engaging selected grooves and a lever 94 permitting selective engagement and disengagement of the release mechanism and the ruler. It would have been an obvious matter of design choice at the time Applicant's invention was made to form the ruler and locking mechanism of a measuring device similar to that of Gerhardt as a flat ruler having a plurality of grooves and a locking mechanism

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configured similar to those taught by Kim, since Applicant has not disclosed that having a ruler with a flat side and a plurality of grooves solves any stated problem or is for any particular purpose, and it appears that the measuring device would perform equally well with a ruler having a flat side with a plurality of grooves and a corresponding locking mechanism as it would with a cylindrical ruler and a corresponding locking mechanism.

11. Claims 8, 9 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrante et al. ('401) in view of Doherty et al. ('545). Ferrante et al. teach all of the limitations of the claims except that the ruler includes a flat side and a series of periodic grooves, and that the release is spring loaded. Doherty et al. teach a gauge device including a pair of arms **10a,12a**, a ruler **37** comprising a flat side and a series of periodic grooves **37a** coupled to the arms, a locking mechanism **36** and handle **38** coupled to the locking mechanism. The locking mechanism includes an opening through which the ruler is received and a spring loaded release mechanism **39** to selectively release the ruler for sliding movement through the opening. The release mechanism includes at least one protrusion for engaging selected grooves and a lever **39** permitting selective engagement and disengagement of the release mechanism and the ruler. It would have been an obvious matter of design choice at the time Applicant's invention was made to form the ruler **28,30** and locking mechanism **26** of a measuring device similar to that of Ferrante et al. as a flat ruler having a plurality of grooves and a locking mechanism configured similar to those taught by Doherty et al., since Applicant has not disclosed that having a ruler with a flat side and a plurality of grooves solves any stated problem or is for any particular purpose, and it appears that the measuring device would perform equally well with a ruler having

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a flat side with a plurality of grooves and a corresponding locking mechanism as it would with a two piece ruler and a corresponding screw locking mechanism.

Allowable Subject Matter

12. Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teach or fairly suggest a method for utilizing a measuring device to facilitate an orthopedic procedure, as claimed by Applicant in claim 28, where the setting step includes selectively locking the noninvasive stop plate to the ruler with a spring biased release mechanism.

Response to Arguments

14. Applicant's argument with respect to the rejection of claim 32 under 35 U.S.C. 112, second paragraph, filed June 18, 2004 has been fully considered but they are not persuasive. Applicant contends that the claim has been amended in the manner suggested by the Examiner. This argument is not persuasive because no amendment to claim 32 has been made.

15. Applicant's arguments with respect to the prior art rejections of claims 1-35 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that

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Engelbrech fails to teach or suggest a locking mechanism that cooperates with the ruler to permit selective adjustment of the distance between the marking guide and the stop plate by moving the stop plate with respect to the ruler. Applicant further contends that neither Engelbrech nor Dale et al. teach or suggest a stop plate that is pivotable to facilitate transverse placement, with respect to the ruler, against an end surface of a bone. These arguments have been considered but are moot in view of the new grounds of rejection set forth hereinabove.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. White ('656) teaches instrumentation and a method for femoral sizing and anterior and distal femoral resections. Masini (179) teaches a bone cutting guide and method to accommodate different-sized implants.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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September 17, 2004